

K091295

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™ XG (v4.0) SSA-790A Ultrasound System

510(k) Summary

MAY 15 2009

Submitter's Name: Toshiba America Medical Systems, Inc.
Address: PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068
Contact: Paul Biggins, Director Regulatory Affairs
Telephone No.: (714) 730-5000

Device Proprietary Name: APLIO XG MODEL SSA-790A Version 4.0
Common Name: Diagnostic Ultrasound System

Classification:

- **Regulatory Class:** II
- **Review Category:** Tier II
- **Ultrasonic Pulsed Doppler Imaging System – Product Code:** 90-IYN
[Fed. Reg.No.: 892.1550]
- **Ultrasonic Pulsed Echo Imaging System – Product Code:** 90-IYO
[Fed. Reg.No.: 892.1560]
- **Diagnostic Ultrasonic Transducer – Product Code:** 90-ITX
[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

- Toshiba Ultrasound Diagnostic System Aplio XG MODEL SSA-790A V3.0 - 510(k) K082119

Device Description:

The Aplio XG v4.0 is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Intended Use:

The Aplio v4.0 is intended to be used for the following type of studies: fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

Safety Considerations:

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-1 (applicable portion), IEC 60601-1-2 (applicable portion), IEC 60601-1-4 (applicable portion), IEC60601-2-37 (applicable portions), IEC 62304 (applicable portion) and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.



MAY 15 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091295

Trade/Device Name: APLIO XG Diagnostic Ultrasound System, Model SSA-790A version 4.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 1, 2009
Received: May 4, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the APLIO XG Diagnostic Ultrasound System, Model SSA-790A version 4.0, as described in your premarket notification:

Transducer Model Number

PST-25BT
PST-30BT
PST-50AT
PST-65AT
PVT-375BT

PVT-375MV
PET-382BT
PVT-382MV
PVT-575MV
PVT-674BT

PVT 661VT
PVT-681MV
PVT-745BT
PVT-770RT
PLT-604AT

PLT-704AT
PLT-704SBT
PLT-705BTH
PLT-705BTF
PLT-805AT

PLT-1202S
PLT-1204AT
PLT-1204BT
PLT-1204AX
PLT-1204BX

PLT-1204MV
PET-510MB
PC-20M
PC-50M

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,



fm Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health.

Enclosure(s)

System: Aplio XG v4.0 SSA-790A

Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											Other [Note]
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	
Ophthalmic												
Fetal	P	P	P	P	P	2	P	P	P	P	P	5,7,8,9,10
Abdominal	P	P	P	P	P	2,3	P	P	P	P	P	5,7,8,9,10
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			4,5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	2,3	P	P	P	P	P	5,7,8,9,10
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,9
Neonatal Cephalic	P	P	P	P	P	3	P	P	P	P		
Adult Cephalic	P	P	P	P	P	3	P	P	P	P		
Trans-rectal	P	P	P		P	2	P	P	P	P	P	4,5,7
Trans-vaginal	P	P	P		P	2	P	P	P	P	P	4,5,7
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P	P		4,5,6,7,9
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P	P		4,5,6,7,9
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P	P	P	2	P	P	P	P		4,5,6,7,9
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

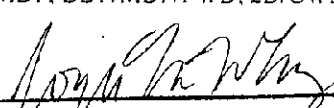
Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR 801.109)


 (Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790ATransducer: PST-25BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	3	P	P	P	P		
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P	P		
Small Organ (Note 1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P	P		
Adult Cephalic	P	P	P	P	P	3	P	P	P	P		
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)

[Signature]
 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091295

System: Aplio XG v4.0 SSA-790ATransducer: PST-30BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	3	P	P	P	P		
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P	P		
Small Organ (Specify) (1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P	P		
Adult Cephalic	P	P	P	P	P	3	P	P	P	P		
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

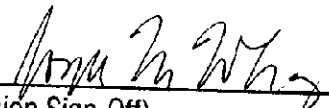
Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR 801.109)


 (Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices510(k) Number K091295

System: Aplio XG v4.0 SSA-790ATransducer: PST-50AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Note 1)												
Neonatal Cephalic	P	P	P	P	P	3	P					
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P					4
Cardiac Pediatric	P	P	P	P	P	3	P					4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

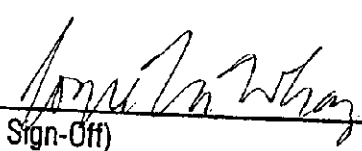
Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices510(k) Number K091295

System: Aplio XG v4.0 SSA-790ATransducer: PST-65AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation		Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M								
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Abdominal)										
Intra-operative (Neuro)										
Laparoscopic										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic	P	P	P	P	P	3	P	P	P	
Adult Cephalic										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Intravascular										
Other (Specify)										
Cardiac Adult	P	P	P	P	P	3	P	P	P	4
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	4
Intravascular (Cardiac)										
Trans-esoph. (Cardiac)										
Intra-cardiac										
Other (Specify)										
Peripheral vessel										
Other (Specify)										

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices510(k) Number 6091295

Prescription Use Only (Per 21 CFR 801.109)

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™ XG (v4.0) SSA-790A Ultrasound System

System: Aplio XG v4.0 SSA-790A

Transducer: PVT-375BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P	P		5, 7
Abdominal	P	P	P		P	2	P	P	P	P		5, 7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P	P		5, 7
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 12091295

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™ XG (v4.0) SSA-790A Ultrasound System

System: Aplio XG v4.0 SSA-790A

Transducer: PVT-375MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N	N	N	5,7,8,9,10
Abdominal	N	N	N		N	2	N	N	N	N	N	5,7,8,9,10
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N	N	N	5,7,8,9,10
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

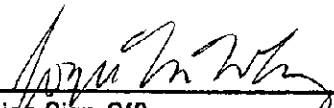
Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

4091295

Prescription Use Only (Per 21 CFR801.109)

System: Aplio XG v4.0 SSA-790ATransducer: PET-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P	P		5
Abdominal	P	P	P		P	2	P	P	P	P		5
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P	P		5
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


 (Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790ATransducer: PVT-382MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation				Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD								
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P	P	P	5,7
Abdominal	P	P	P		P	2	P	P	P	P	P	5,7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P	P	P	5,7
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790A
Transducer: PVT-575MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation					Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD									
Ophthalmic													
Fetal	P	P	P			P	2	P	P	P	P	P	5,7,8
Abdominal													
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric													
Small Organ (Specify) (1)													
Neonatal Cephalic													
Adult Cephalic													
Trans-rectal													
Trans-vaginal													
Trans-urethral													
Trans-esoph. (non-Card.)													
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)													
Intravascular													
Other (Specify)													
Cardiac Adult													
Cardiac Pediatric													
Intravascular (Cardiac)													
Trans-esoph. (Cardiac)													
Intra-cardiac													
Other (Specify)													
Peripheral vessel													
Other (Specify)													

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790A
Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation					Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD									
Ophthalmic													
Fetal	P	P	P			P	2	P	P	P	P		5
Abdominal	P	P	P			P	2	P	P	P	P		5
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	P	P	P			P	2	P	P	P	P		5
Small Organ (Specify) (1)													
Neonatal Cephalic													
Adult Cephalic													
Trans-rectal													
Trans-vaginal													
Trans-urethral													
Trans-esoph. (non-Card.)													
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)													
Intravascular													
Other (Specify)													
Cardiac Adult													
Cardiac Pediatric													
Intravascular (Cardiac)													
Trans-esoph. (Cardiac)													
Intra-cardiac													
Other (Specify)													
Peripheral vessel													
Other (Specify)													

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

Prescription Use Only (Per 21 CFR801.109)

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™ XG (v4.0) SSA-790A Ultrasound System

System: Aplio XG v4.0 SSA-790A

Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P	P		4.5
Trans-vaginal	P	P	P		P	2	P	P	P	P		4.5
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure


Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number 2091295

System: Aplio XG v4.0 SSA-790ATransducer: PVT-68IMV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P	P	P	4,5,7
Trans-vaginal	P	P	P		P	2	P	P	P	P	P	4,5,7
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

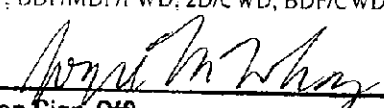
Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices510(k) Number K091295

System: Aplio XG v4.0 SSA-790A
Transducer: PVT-745BTV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation				Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD								
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

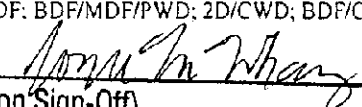
Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

5091295

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio XG v4.0 SSA-790ATransducer: PVT-770RT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation				Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD								
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P			5
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

Prescription Use Only (Per 21 CFR801.109)

System: Aplio XG v4.0 SSA-790ATransducer: PLT-604AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P	P		5
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P	P		5
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P	P		5
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P	P		5
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

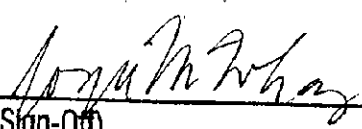
Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790ATransducer: PLT-704AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P	P		5
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P	P		5
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P	P		5
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
	P	P	P		P	2	P	P	P	P		5
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

Prescription Use Only (Per 21 CFR801.109)

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-704SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation					Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD	Color Doppler							
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P	P		5
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P	P		5
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P	P		5
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P	P		5
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR 801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-705BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation					Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD									
Ophthalmic													
Fetal													
Abdominal	P	P	P			P	2	P	P	P	P		5
Intra-operative (Abdominal)	P	P	P			P	2	P	P	P	P		5
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	P	P	P			P	2	P	P	P	P		5
Small Organ (Specify) (1)	P	P	P			P	2	P	P	P	P		5
Neonatal Cephalic													
Adult Cephalic													
Trans-rectal													
Trans-vaginal													
Trans-urethral													
Trans-esoph. (non-Card.)													
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)													
Intravascular													
Other (Specify)													
Cardiac Adult													
Cardiac Pediatric													
Intravascular (Cardiac)													
Trans-esoph. (Cardiac)													
Intra-cardiac													
Other (Specify)													
Peripheral vessel													
Other (Specify)													

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure


Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-705BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation				Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD								
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P	P		5
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P	P		5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P	P		5
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P	P		5
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure


Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices510(k) Number 15091295

System: Aplio XG v4.0 SSA-790ATransducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation				Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD/CWD									
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P	P		5,6,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P	P		5,6,7
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P	P		5,6,7
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P	P		5,6,7
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

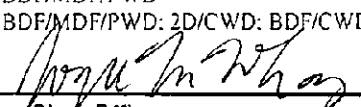
Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices510(k) Number 6091295

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-1202S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation					Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD	Color Doppler							
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			4,5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			4,5
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

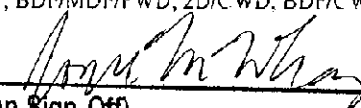
Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-1204AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation				Color Doppler	Combined (Specify) †	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD								
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,6
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			4,5,6
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TD!

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio™ XG (v4.0) SSA-790A Ultrasound System

System: Aplio XG v4.0 SSA-790A

Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,6
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			4,5,6
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

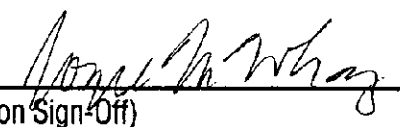
Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number 2091295

System: Aplio XG v4.0 SSA-790ATransducer: PLT-1204AX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation				Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD								
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,6
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			4,5,6
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-I204BX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation				Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD								
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,6,7
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6,7
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			4,5,6,7
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

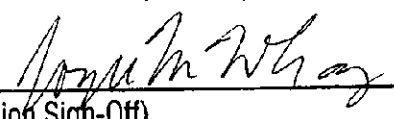
Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

12091295

System: Aplio XG v4.0 SSA-790A
Transducer: PLT-I204MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation				Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD	CWD								
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P		P	5,7,9
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P		P	5,7,9
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P		P	5,7,9
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P		P	5,7,9
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

15091295

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio XG v4.0 SSA-790ATransducer: PET-510MB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											Other [Note]
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

16091295

System: Aplio XG v4.0 SSA-790ATransducer: PC-20M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD/CWD	Color Doppler	Combined: (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]	
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult											P	
Cardiac Pediatric											P	
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091295

System: Aplio XG v4.0 SSA-790ATransducer: PC-50M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation			Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
	B	M	PWD CWD								
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Abdominal)											
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
Small Organ (Specify) (1)											
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skeletal (Conventional)											
Musculo-skeletal (Superficial)											
Intravascular											
Other (Specify)											
Cardiac Adult				P							
Cardiac Pediatric				P							
Intravascular (Cardiac)											
Trans-esoph. (Cardiac)											
Intra-cardiac											
Other (Specify)											
Peripheral vessel				P							
Other (Specify)											

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K082119

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging (New)

Note 8 STIC

Note 9 3D color (New)

Note 10 STIC Color (New)

Prescription Use Only (Per 21 CFR801.109)

Ami M. Whang
(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091295